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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,662	12/20/2001	Michel Pairat	1/1175	1119

28501 7590 09/15/2003

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

10/027,662

Applicant(s)

PAIRET ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-9,12-22,45 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,5-9,12-22,45 and 48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed on 07/02/03 was entered. Claims 2-4, 10-11, 23-44 and 46-47 were cancelled. New claims 49-50 were added.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-9, 12-18, 21-22, 45 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss et al (20020052312 A1) in view of Meissner et al (20020115680 A1).

Reiss teaches methods for the treatment of chronic obstructive pulmonary disease using an oral muscarinic receptor antagonist in combination with at least one other therapeutic agent. Anticholinergic agents such as the quaternary ammonium compounds oxitropium bromide and tiotropium bromide and beta agonists were used in COPD treatments where their combination has resulted in synergistic responses ([0002] to [0003]). Tiotropium bromide is a non-selective muscarinic receptor antagonist (see [0006]).

Reiss discloses a pharmaceutical composition suitable for oral administration comprising a therapeutically effective amount of a muscarinic M3 receptor antagonist in

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combination with a therapeutically effective amount of at least one another therapeutic agent selected from the group consisting of beta-2-agonist and dopamine antagonist (see [0010]). Reiss discloses excipients such as dextran, and mannitol as suitable additives. Also desirable dose for each tablet or capsule is suggested at about 1 to 500 mg of each active agent (see [0043]). Reiss lacks disclosure on specific dopamine antagonists such as talipexol and pramipexol.

Meissner teaches anticholinergics which may be used as medicaments for the treatment of disorders such as asthma or COPD (see [00172]). The suitable examples of **dopamine agonists**, which may optionally be used in conjunction with the anticholinergics, include **pergolide, bromocriptine, talipexol, viozan and pramipexol** (see [0178]). Suitable preparations for administration of the formulations are such as tablets, capsules and inhalation (see [00184]). Capsules containing one or more active substances or combinations of active substances may for example be prepared by mixing the active substances with inert carriers such as lactose or sorbitol and packing them into gelatine capsules (see [0187]). When administered by inhalation the compounds are characterized by high efficacy even at doses in the  $\mu\text{g}$  range or higher doses in the range of 1 to 1000 mg (see [0189]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings of Reiss on method of treating COPD by administering a combined therapy of anticholinergics such as tiotropium bromide and

a dopamine agonist to have looked in the art for specific dopamine agonists suitable for combination with anticholinergics as taught by Meissner, with the reasonable expectation of successfully preparing an effective combination therapy specific for a disorder.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined references as applied to claims 1, 5-9, 12-18, 21-22, 45 and 48-50 above, and further in view of Schmelzer et al (20020193392 A1).

The combined references, discussed above, lack specific disclosure on preferred particle size.

Schmelzer discloses a pharmaceutical composition comprising a tiotropium salt and a salmeterol salt. The preferred dosage form is inhalable powders where the powders have a maximum mean particle size of up to 250  $\mu\text{m}$ , preferably between 10 and 150  $\mu\text{m}$  (see [0006] and [0028]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of the combined references on compositions and method of treating respiratory disorders by administering a combined active agent formulation via inhalation by implementing the preferred particle size as taught by Schmelzer because of successfully preparing a formulation that would reach the desired site.

***Response to Arguments***

Applicant's arguments with respect to claims 1-9, 12-22, 45 and 48 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

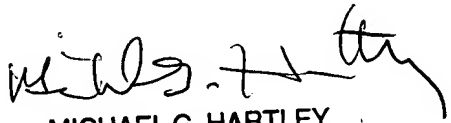
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian  
August 27, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER